DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER 250 Marquette Avenue, Suite 600 Minneapolis, MN 55401 (612) 334-4100 Fax:(612) 334-4134 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 02/14/2013 - 04/03/2013* FEI NUMBER 2182207
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED **TO:** Omar S. Ishrak, Chairman and Chief Executive Officer	
FIRM NAME Medtronic Neuromodulation	STREET ADDRESS 7000 Central Ave NE
CITY, STATE, ZIP CODE, COUNTRY Minneapolis, MN 55432-3568	TYPE ESTABLISHMENT INSPECTED Medical Device Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

Products that do not conform to specifications are not adequately controlled.

Specifically,

A) Your firm distributed nonconforming SC catheters, and failures due to the nonconforming products have resulted in serious adverse events. From September 10, 2012 to March 25, 2013, approximately (b) (4) SC catheters that do not confirm to the current product specifications have been distributed. Regulatory approval was received for Supplement 136 to PMA P860004 on December 15, 2011 to change the design of SC Catheter models 8709SC, 8731SC, 8596SC, and 8578 to mitigate a known field issue associated with CAPA 1507- SC Catheter Occlusion. This design change was implemented via ECO 12-00985, dated March 6, 2012, and the new revisions of Catheter models were released to the field in September 2012. However, the previous SC catheter models which do not conform to the current design have continued to be distributed and have attributed to 60 complaints of catheter occlusion since September 2012.

B) Your firm distributed approximately (b) (4) lead kits containing nonconforming lead caps to the field from 19 NOV 2012 to 29 JAN 2013. On 31 OCT 2012 and 19 NOV 2012, your firm performed testing on the DBS lead cap that showed the (b) (4) The product specification contains (b) (4) requirement of (b) (4) [redacted]

Per your procedure "QMS1340 TLP Escalating Quality Issues and Handling Nonconformances" ver. 9.0 dated 1/11/12, when

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a product nonconformance is confirmed, the product is to be segregated and place on hold. If the product has been distributed, the risk assessment decision must be documented within 30 days. The Risk Assessment for DBS Lead CAP (b) (4) Issue (GCAPA 145631) was not completed until 28 JAN 2013.

In addition, your procedure also requires an approved product deviation to distribute nonconforming product. A product deviation for the nonconforming DBS lead kits was not authorized until 07 FEB 2013.

OBSERVATION 2

Procedures for corrective and preventive action have not been adequately established.

Specifically,

(A) Actions needed to correct and prevent recurrence of a quality problem were identified but not implemented. For example,

(i) Feedthrough CAPA number 10594 identified actions on 02 APR 2008 via NDHF1148-98756- "Feed Through Shorting, (b) (4) Effectiveness Report" to correct and prevent recurrence of feedthrough shorting resulting in motor stalls in the SynchroMed II infusion pump. The recommended action of (b) (4) has not been implemented. Since April 2008, at least 298 serious adverse events have resulted from feedthrough shorting.

(ii) CAPA 110407-(b) (4) identified an action within the 21 JUN 2012 Risk Evaluation Board meeting minutes. The recommended action was (b) (4). The NLT did not approve the recommendation and delayed any action until the HHA was completed ~~upon our request~~ 4/3/13 4/3/13. during this inspection. Since June 2012, at least 37 serious adverse events have been "possibly" related to the (b) (4) CAPA.

(B) The Health Hazard Assessments for high priority CAPAs with the highest patient severity of death were not completed

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in a timely fashion. Your procedure, QMS1002 TLP Corrective and Preventive Actions requires an HHA for any high priority CAPA with a patient risk. For example:

(i) "CAPA 110407(b) (4)" was opened on 01 NOV 2011. The HHA for this CAPA was not completed until 11 MAR 13 (during this inspection.)

(ii) "CAPA 132952(b) (4) was opened 26 June 2012. The HHA was completed on 01 FEB 13.

(C) Health Hazard Assessments have not been updated after CAPA effectiveness monitoring signaled an increase in the rate of occurrence as evidenced by CAPAs 3064, 7685, and 1507. QMSWI14505 "CAPA Monitoring" states, "Update Health Hazard Analysis document MEDN-0255, if required by identification of a new hazard / harm and or an increase in severity or occurrence defined by a change in color on the Risk Index table."

(i) In February 2011, your firm detected a signal in the CAPA 1507 monitor showing a(b) (4). The 13 FEB 2012 High Priority CAPA Board recommended that the HHA for CAPA 1507 "SC Catheter Occlusion" be updated. The HHA has not been updated since September 2008. At least 300 complaints for this CAPA have been received since the HHA was last updated.

(ii) In February 2012, a signal was detected in the CAPA3064 monitor showing a(b) (4). The signal investigation was not completed until February 2013, and the HHA has not been updated since March 2009. At least 140 complaints for this CAPA have been received since the HHA was last updated.

(iii) In February 2011, your firm opened a CAPA monitor for CAPA 7685(b) (4). In December 2011, a decision was made to update the HHA for CAPA 7685; however, the HHA has not been updated since September 2010. At least 40 complaints for this CAPA have been received since the HHA was last updated.

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(D) Your firm did not perform a complaint search for CAPA 110407-(b) (4) from December 2011 until our request during this inspection. Your procedure, QMS1861, Corrective and Preventive Action (CAPA) Procedure, versions 11.0 and 12.0 states, "NOTE: The first PE search must take place within 90 days after the CAPA Start Date…an additional PE search must be performed at least every 90 days during the investigation phase and documented in the CAPA record."

OBSERVATION 3

Design verification does not confirm that design output meets design input requirements.

Specifically, design verification testing was never performed on the DBS lead cap to verify that the (b) (4) requirement was met. A total of 103 complaints including 11 serious adverse events have been reported since the lead cap was released in May 2006.

OBSERVATION 4

Procedures for design change have not been adequately established.

Specifically, testing was not performed to verify that a design change did not adversely affect the product. Your firm changed (b) (4) on the DBS lead extensions and lead caps from a (b) (4) to a (b) (4) in January 2011. Seventy-five of the 103 complaints regarding connector block twisting and subsequent DBS lead damage have been reported since the release of the (b) (4) in February 2011.

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Observation Annotations

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Observation ~~1~~ 2: Promised to correct.
Observation ~~3~~ 4: Promised to correct.
4/3/13 4/3/13

Observation ~~2~~ 3: Promised to correct.
observation 1: Blank

*** DATES OF INSPECTION:**
02/14/2013(Thu), 02/15/2013(Fri), 02/19/2013(Tue), 02/20/2013(Wed), 02/22/2013(Fri), 02/25/2013(Mon), 02/26/2013(Tue), 02/28/2013(Thu), 03/01/2013(Fri), 03/04/2013(Mon), 03/07/2013(Thu), 03/11/2013(Mon), 03/13/2013(Wed), 03/14/2013(Thu), 03/21/2013(Thu), 03/26/2013(Tue), 03/28/2013(Thu), 04/03/2013(Wed)

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